UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL ACTIONS	

MEMORANDUM IN SUPPORT OF DEFENDANT AMGEN INC.'S MOTION TO DISMISS

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Defendant, Amgen Inc. ("Amgen"), pursuant to Federal Rules of Civil Procedure ("FRCP") 9(b) and 12(b)(6), submits this Memorandum in Support of its individual Motion to Dismiss the Master Consolidated Class Action Complaint (the "Complaint"). 1/

I. The Complaint Must Be Dismissed Under FRCP 12(b)(6) As to Medicare Reimbursements and Co-Pays Relating to Amgen's Product EPOGEN®.

The Complaint must be dismissed to the extent that it purports to seek recovery based upon Medicare reimbursements and co-pays for Amgen's product, EPOGEN® (Epoetin alfa). 2/ Medicare does not base reimbursement for EPOGEN® on AWP, as Plaintiffs claim. Instead, the Medicare reimbursement rate for EPOGEN® provided to dialysis patients was specifically established by Congress at $10 per 1,000 units – a rate that has remained unchanged since 1993. *See* 42 U.S.C. § 1395rr(b)(11)(B). Given that the rate was set by Congress, and not based on EPOGEN®'s AWP, it is impossible for Amgen to have "manipulated" or "artificially inflated" Medicare reimbursement for EPOGEN's®, as Plaintiffs have alleged. While perhaps more broadly reflective of the lack of care that went into Plaintiffs' decision to sue Amgen in the first place, the claim that Amgen inflated Medicare payments by manipulating EPOGEN®'s AWP fails as a matter of fact and of law and must be dismissed.

1/ Amgen has also joined in the Consolidated Motion and Memorandum in Support of Defendants' Motion to Dismiss the Master Consolidated Class Action Complaint, incorporated herein by reference. This motion raises issues unique to Amgen.

2/ As noted in the Complaint, there are two brands of Epoetin alfa. Amgen markets its brand, EPOGEN®, only for treatment of anemia in dialysis patients. Ortho Biotech, a subsidiary of Johnson and Johnson, markets the other brand of Epoetin alfa, Procrit®, for non-dialysis uses, under license from Amgen. Amgen makes no pricing decisions relating to Procrit®.

II. As to Amgen, the Complaint Fails to Comply with FRCP 9(b).

However the Complaint measures up as a whole under FRCP 9(b), its allegations as to Amgen in particular fall short of the mark. 3/ Unlike the allegations against virtually every other defendant (which fail in any event to satisfy Rule 9(b)), Plaintiffs cannot allege anything more than that Amgen manufactures two branded products, EPOGEN® and NEUPOGEN®, and that EPOGEN® accounted for a significant percentage of Medicare expenditures in 1999.

The paucity of facts tying Amgen to the purported industry-wide "scheme" alleged in the Complaint is evident on the face of the three paragraphs devoted to Amgen. In sum, they allege that:

> Amgen is identified in certain publications as the sole manufacturer of the drug Filgrastim (sold by Amgen as NEUPOGEN®), and as one of two sources of the drug Epoetin alfa (sold by Amgen as EPOGEN®), Cplt. ¶ 192;
>
> According to a September 2001 GAO report, EPOGEN® accounted for the second highest percentage of Medicare expenditures on drugs in 1999, Cplt. ¶ 193; and,
>
> Amgen reported allegedly inflated AWPs for EPOGEN® and NEUPOGEN®, and "market[ed] the resulting spread to increase the market share of its drugs," thereby resulting in "excessive overpayments by Plaintiffs and the Class," Cplt. ¶¶ 192, 194.

There are *no* other allegations, specific or otherwise, in support of Plaintiffs' fraud claim against Amgen. The Complaint does not identify, for example: (1) a single specific

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3/ FRCP 9(b) requires that, "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." FRCP 9(b) requires that a complaint purporting to allege fraud must "'(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997) (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1127-28 (2nd Cir. 1994) (internal quotation marks and citations omitted)); *see also McGinty v. Beranger Volkswagen, Inc.*, 633 F.2d 226, 228 (1st Cir. 1980).

instance in which Amgen allegedly engaged in fraud; (2) a single source of the alleged fraud; (3) when and where the alleged fraud was committed; or, (4) why any alleged acts or statements were fraudulent, each of which must be alleged with particularity to state a viable claim for fraud under FRCP 9(b). *See Suna*, 107 F.3d at 68. Plaintiffs fail to identify a single reported AWP for an Amgen product that was false, who at Amgen was allegedly involved in misrepresenting AWP, when the supposed misrepresentations were made, or to whom they were made. The Complaint merely asserts a bald, conclusory allegation that Amgen fraudulently inflated AWPs for EPOGEN® and NEUPOGEN® without alleging any facts specific to Amgen to support that claim. A charge of fraud "may not be based upon speculation or conclusory allegations." As this Court has itself observed, without more, such claims are insufficient under Rule 9(b). *United States ex. rel. Walsh v. Eastman Kodak Co.*, 98 F.Supp. 2d 141, 147 (D. Mass. 2000) (*citing United States ex. rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)). *See also Suna*, 107 F.3d at 68; *McGinty*, 633 F.2d at 227-29.

The utter absence of detail as to Amgen stands in stark contrast to the at least arguably more detailed allegations of fraud against the other defendants. 4/ To buttress their allegations of fraud against Amgen's co-defendants, Plaintiffs cite to, quote, and frequently memorialize in charts (1) congressional "findings" of price manipulation by specific defendant manufacturers in relation to specific drugs (*see, e.g.*, Cplt. ¶¶ 184, 205, 220, 299, 301-303, 312, 319); (2) investigative findings, including findings of the U.S. Department of Justice and/or HHS OIG, that specific defendant manufacturers created and marketed a "spread" between AWP and "actual AWP" that ranging from 20% to 54,199%, depending on the drug (*see, e.g.*, Cplt.

4/ Amgen's reference to the allegations against other defendants is for comparison purposes only and should not be construed as suggesting that the Complaint as to any defendant, comports with the requirements of Rule 9(b). It does not. *See* Defendants Consolidated Motion and Memorandum at 44ff.

¶ 190, 206, 208-210, 216-217, 221-223, 231, 234-235, 238-240, 247-248, 251, 256-257, 259-260, 295, 300, 304-308, 314-317, 322-323, 326-327); (3) internal documents allegedly generated by specific defendant manufacturers acknowledging the difference between purchase price and AWP for certain drugs at various volume levels, and encouraging the maintenance and marketing to physicians of a "spread" for particular drugs (*see, e.g.*, Cplt. ¶¶ 196, 197, 198, 207, 213-215, 241, 255, 261, 274-275, 277-279, 320-321); and (4) memoranda from specific defendant manufacturers to providers explaining how they could profit from the spread (*see, e.g.*, Cplt. ¶¶ 199-202, 207, 213-215, 242, 255, 262-266). By contrast, and apart from Amgen's success in the marketplace (which Plaintiffs apparently equate to evidence of fraud), no similar allegations are made as to Amgen. Despite the passage of more than nine months and more than adequate opportunity to investigate and develop a good faith basis for naming Amgen in the Complaint, Plaintiffs do not and cannot set forth a single specific allegation of how Amgen supposedly engaged in the AWP "scheme" broadly alleged in their Complaint.

Instead, Plaintiffs are content to charge Amgen with fraud on nothing more than the fact that Amgen is a successful manufacturer of pharmaceuticals. This is, pure and simple, nothing more than guilt-by-association, and cannot withstand challenge under Rule 9(b). Whatever Plaintiffs' allegations against <u>others</u>, those allegations cannot serve as a basis for alleging fraud as to <u>Amgen</u>. Plaintiffs may not, as they attempt to do here, utilize these allegations of fraud against other defendants or against the monolithic "defendants" generally to maintain a fraud case against Amgen. Otherwise, the very language and purpose of Rule 9(b) would be eviscerated. Treating all defendants as one by lumping them together is clearly insufficient to state a fraud claim under Rule 9(b). *See Goren v. New Vision Int'l, Inc.*, 156 F.3d 721, 730 (7th Cir. 1998) ("... for the most part, the amended complaint simply treats all the

defendants as one; such "lumping together" of defendants is clearly insufficient to state a RICO claim under §1962(c).") (*citing Viacom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 777-778 (7th Cir. 1994); *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d. Cir. 1993) ("Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent statements to "defendants."")).5/ Plaintiffs' failure to muster any particular factual allegations of wrongdoing *by Amgen* is fatal to their claim.

III. Plaintiffs Lack Standing to Sue Amgen.

None of the Plaintiffs allege that they (or their members) paid, in whole or part, for any drug manufactured or distributed by Amgen. Although two Amgen products are named in the Complaint, there is no specific allegation that any plaintiff purchased either of these products. Absent such an allegation, the plaintiffs lack Constitutional Article III standing and standing under RICO to pursue their claims. 6/

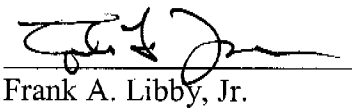
IV. Conclusion.

WHEREFORE, for the foregoing reasons and for the reasons set forth in the Consolidated Motion to Dismiss Master Consolidated Class Action Complaint, in which Amgen has joined, Amgen respectfully requests that its Motion to Dismiss be granted and the Complaint dismissed with prejudice.

5/ This rule is followed in this Circuit. *Goebel v. Schmid Bros.*, 871 F. Supp. 68, 73 (D. Mass. 1994) ("When multiple defendants are involved in cases arising in this circuit, Rule 9(b) requires that fraud be alleged particularly as to each defendant.") (*citing Fleet Credit Corp. v. Sion*, 893 F.2d 441, 444-445 (lst Cir. 1990)); *see also Kuney Int'l S.A. v. DiIanni*, 746 F.Supp. 234, 237 (D. Mass. 1990); *Sebago, Inc. v. Beazer East Inc.*, 18 F.Supp. 2d 70, 79 (D. Mass 1998); *Margaret Hall Foundation v. Atlantic Fin. Mngmt., Inc.* 572 F.Supp. 1475, 1481 (D. Mass. 1983); *Loan v. Federal Deposit Ins. Corp.*, 717 F. Supp. 964, 968 (D. Mass. 1989); *Hurley v. Federal Deposit Ins. Corp.*, 719 F.Supp 27, 31 (D. Mass. 1989); *Greebel v. FTP Software, Inc.*, 182 F.R.D. 370, 374 (D. Mass. 1998), *aff'd*, 194 F.3d 185 (1st Cir. 1999).

6/ Amgen relies upon and adopts the arguments more fully elaborated by Bayer Corporation in its Memorandum in Support of its Motion to Dismiss.

Respectfully submitted,



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